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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,720	12/01/2000	Steven K. H. Foung	2002850-0009	5311

7590 07/12/2005
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EXAMINER

BROWN, TIMOTHY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,720	Applicant(s) FOUNG ET AL.	
	Examiner Timothy M. Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,12,14-22,25-28,92,93,95,97 and 103-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,12,14-22,25,28,92,93,95,97 and 103-107 is/are rejected.
- 7) ☒ Claim(s) 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Non-Final Office Action is responsive to the communication mailed January 14, 2005. Claims 1, 8, 9, 12, 14-22, 25-28, 92, 93, 95, 97, 103-107 are under Examination.

Claim Objections

Claims 26 and 27 are objected to for depending from a rejected base claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 92, 93, 95, 97, 103-105 and 107 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed to non-statutory subject matter because they read on serum which is a product of nature. The claims recite “[a] combination of two or more isolated antibodies . . .” selected from (among others) CBH-2 and CBH-4G, or antibodies that recognize the same epitopes as CBH-2 and CBH-4G. Like the claimed invention, serum from an individual infected with HCV comprises a combination of antibodies. These serum antibodies would bind the same epitopes as those recognized by CBH-2 and CBH-4G. Thus, claims 92, 93, 95, 97, 103-105 and 107 are rejected as being drawn to a non-statutory product of nature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 93, 95, 97, 103-105 and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta et al. (US 5,308,750). As noted above, claims 92, 93, 95, 97, 103-105 and 107 are drawn to a product of nature in that these claims read on human serum from an individual infected with HCV. Mehta et al. disclose isolating human serum from an individual infected with HCV (col. 14, lines 56-65). Thus, Mehta et al. anticipate the subject matter of claims 92, 93, 95, 97, 103-105 and 107.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8, 9, 12, 14-22, 25, 28 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (US 5,308,750).

Claims 1, 8, 9, 12, 14, 25, 28 and 106 are drawn to an isolated antibody that (1) binds to a conformational epitope of HCV E2 protein, wherein the epitope is expressed in more than one HCV genotype, and wherein the antibody is selected from CHB-2, -4G, -5, -7, -8C and -11, or (2) binds to the same conformational epitope as the antibody selected from CHB-2, -4G, -5, -7, -8C and -11. The claims provide that the antibody may recognize an epitope within the region 411-644, or the region 470-644. The claims also provide that the antibody may be monoclonal or derived from a mammal.

Mehta et al. disclose many of the claimed features including purified monoclonal antibodies directed against HCV E2 polypeptides (col. 4, lines 30-34; col. 11, lines 41-45; and col. 13, lines 41-62). Mehta et al. further disclose an antibody selected from CHB-2, -4G, -5, -7, -8C and -11, or an antibody that recognizes the same epitope as one of these antibodies. That is, Mehta et al. disclose an antibody that recognizes an HCV epitope between positions 607-627 (see col. 11, lines 25-32). Mehta et al. do not expressly disclose isolating this antibody as required by the claims. However, Mehta et al. teach that the HCV epitope from positions 607-627 reacts with human sera. Mehta et al. further teach using reactive HCV epitopes to manufacture antibodies for use in HCV diagnostic kits (col. 4, lines 30-33). Thus, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art to use the epitope defined by position 607-627 to manufacture and isolate antibody for the purpose of providing an HCV diagnostic. Note that one skilled in the art would have a reasonable

expectation of success in manufacturing an isolated antibody against position 607-627; Mehta et al. show that this position is antigenic as it reacts with human antibody.

Mehta et al. discloses the limitations of claims 15-22 in that Mehta et al. disclose manufacturing monoclonal HCV antibodies using mammalian hybridomas.

Response to Arguments

The rejection of claims 1, 8, 9, 12, 14, 25, 26, 28 and 106 under 35 U.S.C. 101 is withdrawn in view of Applicants' amendment. The objection of claims 15-22 for depending from a rejected base claim has been rendered moot. This objection has been made moot by the rejection of claims 15-22 under 35 U.S.C. 103. Note that the objection of claim 27 is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

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TMB
7/10/05


JAMES HOUSEL 7/11/05
SUPERVISORY PATENT EXAMINER
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